



## Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

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| <b>Agency name</b>                                 | Virginia Department of Health  |
| <b>Virginia Administrative Code (VAC) citation</b> | 12 VAC 5-70 (Current)<br>12 VAC 5-71 (Proposed Emergency Regulation)   |
| <b>Regulation title</b>                            | Regulations Governing Virginia Newborn Screening Services  |
| <b>Action title</b>                                | Replace existing regulation with emergency regulation to comply with Code of Virginia mandated newborn screening expansion by March 1, 2006. Notice of intent to begin process to make emergency regulation permanent. |
| <b>Document preparation date</b>                   | August 15, 2005  |

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Preamble

*The APA (Code of Virginia § 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.*

- 1) Please explain why this is an "emergency situation" as described above.
- 2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

An emergency regulation is necessary to meet statutory changes affecting newborn screening in the Commonwealth. Chapter 721 of the 2005 Acts of Assembly (House Bill 1824) amended and reenacted Sections 32.1-65 through 32.1-67.1 of the Code of Virginia to expand newborn screening by March 1,

2006. The Board of Health is mandated to promulgate regulations to implement provisions of the act to be effective within 280 days of the enactment. Emergency regulations, therefore, are necessary to meet these mandated timelines.

The current regulation will be repealed and replaced with a new emergency regulation because of the extensive changes to the regulation text.

The emergency regulation will list the specific disorders for which screening will be done on all infants born in the Commonwealth. Previously, newborn screening disorders were referenced directly in the Code of Virginia. The emergency regulation will expand upon existing regulation chapters and add chapters mandated by the Code to address follow up, referrals, and treatment services available for infants and children with conditions identified through newborn screening.

The agency intends to make the emergency regulation permanent.

### Legal basis

*Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

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In addition to the emergency authority described in the previous section, the State Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section 32.1-12 of the Code of Virginia. The Board adopted the emergency regulations at a regularly-scheduled meeting held on July 22, 2005.

### Purpose

*Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.*

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The emergency regulation, proposed to replace the existing regulation, will provide governance for Virginia Newborn Screening Services, a state mandated program administered by the Department of Health.

Virginia Newborn Screening Services is undergoing the most significant expansion in its history from the current panel, which screens for 12 disorders (including hearing screening), to an expanded panel, which will screen for 29 disorders. In concurrence with a 2004 Joint Commission on Health Care study, legislation passed during the 2005 General Assembly directed the department to expand newborn screening in promotion of early detection of treatable conditions. The expansion is to be consistent with the uniform core panel recently recommended in a 2005 report entitled "Newborn Screening: Toward a Uniform Screening Panel and System," which was commissioned by the US Department of Health and Human Services. The proposed emergency regulation will provide official notice for the conditions that the Commonwealth tests blood spots of all newborns. In the past, newborn screening conditions had been listed in the Code; however, with the breadth of the current expansion and possibilities for further increases as technology continues to advance, listing of conditions will be promulgated through the regulatory process.

The proposed emergency regulation will further detail responsibilities of parties involved in newborn services, such as hospitals, primary care providers, and the testing laboratory. This is needed to address the level of change the services are undergoing. In addition, the federal newborn screening report referenced previously provides guidance to states to develop minimum standards and model policies and procedures. This guidance is incorporated as necessary into the proposed emergency regulations.

The proposed emergency regulation will address services available for infants and children who have selected heritable disorders and genetic diseases diagnosed through newborn screening services. Previously, the Code of Virginia stipulated special formula and low protein food benefits for children and pregnant women. The proposed emergency regulation specifies that residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through newborn screening services are referred to the Care Coordination for Children network for care coordination services. The intent is to describe diagnostic, case management, and financial treatment assistance that the department will be responsible to provide or assure in a consistent format. The Code states that all diagnosed individuals are eligible for the children with special health care needs program. The intent is to strengthen linkages to an umbrella of services routinely made available to all special needs children, including infants diagnosed through newborn screening. In addition, the proposed emergency regulation seeks to make the assistance available equitably, regardless of disorder. Financial treatment assistance through the children with special health care needs program is means tested and available for children of families at or below 300% federal poverty level.

**Substance**

*Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons why the regulation is essential to protect the health, safety, or welfare of Virginians. Delineate any potential issues that may need to be addressed as a permanent final regulation is developed.*

For an explanation of changes to the existing regulations (contained in 12 VAC 5-70), see the following chart:

| <b>Current section number</b> | <b>Proposed new section number, if applicable</b> | <b>Current requirement</b> | <b>Proposed change and rationale</b>   |
|-------------------------------|---|----------------------------|--|
| 12VAC5-70-10                  | 12VAC5-71-10                                      | Definitions                | Definitions will be expanded considerably to explain services operating under expanded newborn screening panel. Several definitions no longer in use will be deleted.  |
| 12VAC5-70-20                  | 12 VAC 5-71-100 through 140                       | General Information        | The current section describes authority, purpose, administration, and application. In the proposed regulation, these sections are deleted because they may be considered obsolete by the Code Commission, as those sections do not convey an instruction. Proposed sections outline general information on multiple department programs' responsibilities related to newborn screening services. These responsibilities are clarified by specific entity in the proposed sections and described below in detail. |
| 12VAC5-                       | 12VAC5-71-  | Testing                    | The current section describes minimal  |

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| 70-30        | 20 through 90            |   | provisions for who is tested, exemptions, laboratory services, and timing of testing. Proposed sections separate these provisions and are described below in detail.   |
| 12VAC5-70-40 | 12VAC5-71-40 through 90  | Reports and notifications   | The current section requires the reports be sent to hospitals and healthcare providers. It authorizes establishment of protocols by the department for other notifications. These responsibilities are clarified for each specific entity in the proposed sections and described below in detail.  |
| 12VAC5-70-50 | 12VAC5-71-40 through 140 | Services and treatment provided   | This current section requires the department to provide services of appropriate professionals to manage persons with diseases specified and to provide these services at no direct cost to medically indigent families. These responsibilities are clarified by specific entity in the proposed sections and described below in detail.  |
|              | 12VAC5-71-20             | Core panel of heritable disorders and genetic diseases  | This proposed section lists the conditions (28) for which the newborn-dried-blood-spot testing is conducted. These conditions are based upon federal recommendations as mandated by Chapter 721 of 2005 Acts of Assembly. Previously listed individually in the Code, the disorders tested for will be maintained in the regulation, due to the scope of the expansion and the possibility for further change. |
|              | 12VAC5-71-30             | Religious exemption   | This proposed section provides for the refusal of testing and documentation due to religious beliefs as mandated by § 32.1-65 of the Code of Virginia.   |
|              | 12VAC5-71-40             | Responsibilities of the physician or midwife  | This proposed section states that the physician, certified nurse midwife, or midwife who is licensed by the Board of Medicine in charge of the infant's care after delivery is responsible for causing the specimen for newborn screening to be collected and submitted as mandated in § 32.1-65 of the Code of Virginia.  |
|              | 12VAC5-71-50             | Responsibilities of the first attending healthcare provider                                       | This proposed section clarifies that for infants born outside of the hospital, the first attending healthcare provider as defined in 12VAC5-71-10 has the responsibility to cause the specimen to be collected and submitted.  |
|              | 12VAC5-71-60             | Newborn dried blood-spot screening collection and submission and notification—hospital deliveries | This proposed section outlines appropriate time intervals for specimen collection and makes specific circumstantial provisions (e.g. premature infants) for infants who are born in hospitals. This section also assigns responsibility for collection of primary and necessary repeat specimens and communication responsibilities among  |

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|  |               |  | multiple providers caring for the newborn.  |
|  | 12VAC5-71-70  | Newborn dried blood-spot screening collection and submission and notification—deliveries outside of the hospital | This proposed section outlines appropriate time intervals for specimen collection and makes specific circumstantial provisions (e.g. premature infants) for infants who not born in hospitals. This section also assigns responsibility for collection of primary and necessary repeat specimens and communication responsibilities among multiple providers of the newborn's care. |
|  | 12VAC5-71-80  | Responsibilities of the chief executive officer  | This proposed section assigns responsibility for hospitals to have policies and procedures for collection, notification, communication, and training related to newborn screening services.   |
|  | 12VAC5-71-90  | Responsibilities of the testing laboratory   | This proposed section outlines responsibilities of the contract laboratory to the department. Section 32.1-65 of the Code of Virginia authorizes the tests to be performed by the Division of Consolidated Laboratory Services.   |
|  | 12VAC5-71-100 | Reporting to the commissioner  | This proposed section outlines reporting duties as specified in § 32.1-66   |
|  | 12VAC5-71-110 | Scope and content of Virginia Newborn Screening Services   | This proposed section outlines the responsibilities of the department with regard to follow up, diagnosis, data collection, education, referrals, and treatment services available.   |
|  | 12VAC5-71-120 | Responsibilities of the Pediatric Comprehensive Sickle Cell Clinic Network                                       | This proposed section outlines the responsibilities of this program with regard to consultation to primary care providers, family counseling and support, scheduled clinics, and referral to inpatient care facilities.   |
|  | 12VAC5-71-130 | Responsibilities of metabolic treatment and genetic centers facilities   | This proposed section outlines the responsibilities of department-contracted centers with regard to clinical services, including consultation to health care providers, family counseling and support, schedule clinics, inpatient care facilities, clinical genetic services, and nutritional counseling.  |
|  | 12VAC5-71-140 | Responsibilities of the Care Connection for Children network   | This proposed section outlines the responsibilities of this program with regard to care coordination services for those cases referred by newborn screening services.   |
|  | 12VAC5-71-150 | Use of federal, state, or other resources  | This proposed section authorizes use of federal Title V maternal and child health block grant funds and other funds as sought and received to provide newborn screening services.   |
|  | 12VAC5-71-160 | Confidentiality of information   | This proposed section states newborn screening record maintenance, storage and safeguard requirements.  |
|  | 12VAC5-71-170 | Documents incorporated by reference  | This proposed section references the report outlining federal recommendations for   |

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|  |  | newborn screening expansion also referenced in § 32.1-65 of the Code. |
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**Alternatives**

*Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.*

No alternatives to promulgating this regulation exist. The regulation is mandated by the third enactment of Sections 32.1-65 through 32.1-67.1 of the Code of Virginia from the 2005 Acts of Assembly (Chapter 721).

**Family impact**

*Please assess the impact of the emergency regulatory action on the institution of the family and family stability.*

The regulation provides for expanded testing of newborns for selected heritable disorders and genetic diseases. Expanded testing will facilitate early identification of such disorders. Conditions were added to the testing panel based on a 2005 federal study and report entitled “Newborn Screening: Toward a Uniform Screening Panel and System.” The recommended conditions were selected based on the following criteria: (1) clinical characteristics (e.g., incidence, burden of disease if not treated, phenotype (observable characteristics) in the newborn); (2) analytical characteristics of the screening test (e.g., availability and features); and (3) diagnosis, treatment, and management of the condition in both the acute and chronic forms, including the availability of health professionals experienced in diagnosis, treatment, and management. Expanded testing should improve the health of newborns, reduce morbidity and mortality from these conditions, and contribute to an overall positive impact on families.

In some cases, families will receive screening results that require further testing. Families whose infants will be found not to have these diseases after further testing may experience some distress during the diagnostic testing phases and may incur financial costs associated with such testing. National studies, however, have found an overall positive cost benefit when weighing the stresses that may be caused by initial false positives, versus the benefits of identification and early treatment for infants who have these diseases.

Although the testing is mandated by the Code of Virginia, provisions remain in the statute for parents to refuse newborn screening if the test conflicts with his religious practices or tenets.

Chapter 721 of the 2005 Acts of Assembly mandates that all infants diagnosed through newborn screening services become eligible for the department’s children with special health care needs program. Benefits for special metabolic formulas and low protein modified foods had previously been limited to specific diseases in the Code; until now Code language provided that families of children and pregnant women with phenylketonuria could purchase metabolic formulas at no more than 2% of their gross annual income. In addition, these families were eligible for financial reimbursement from the department of up to \$2,000 annually for purchase of low protein modified foods. With the expansion of newborn screening services, these specific provisions were removed and treatment was mandated to be addressed in regulation. This provides the department the ability to address the full array of services that may be required by various conditions.

By facilitating entry into the larger children with special health care needs program, families will be better linked with available care coordination services, which includes the services of an insurance benefits specialist to help them apply for available programs and fully utilize the health benefits they have or obtain.

In addition, the children with special health care needs program currently provides a Pool of Funds to help families at or below 300% federal poverty level whose children are uninsured, or underinsured to help pay for medical services. Such payment currently may support hospitalizations, medications, further diagnostic testing, durable medical equipment, and nutritional therapies.

Providing special metabolic formulas through this model will result in changes to the current formula program, which is now centrally and separately administered. Currently, 98 participants receive metabolic formulas through the central program. Of these persons, 69 are children under the age 21 who would qualify for the services of the children with special health care needs program. All families of these children would receive care coordination services and family-to-family support services. In this group, 11 are known to be covered under Medicaid and would continue to have medical services and metabolic formulas covered under Medicaid. In addition, 28 persons would qualify under the current Pool of Funds guidelines to have their metabolic formulas covered. VDH would be increasing its costs over the current program by \$15,650. In this group, however, 19 appear to be at 200% or below federal poverty level and may be eligible for FAMIS Plus (Medicaid) or FAMIS. care coordinators would help these families pursue enrollment in applicable programs. Of the 69 children currently receiving formula through the centrally administered program, 30 appear to have family incomes above 300% federal poverty level, which would make them ineligible for coverage for metabolic formulas through the Pool of Funds. Twelve of these families have incomes exceeding \$100,000 annually. The 30 families with incomes above 300% federal poverty level would no longer receive a formula subsidy as in the current system. VDH would be reducing its costs by \$67,000 for this cohort. The average family would be paying an additional \$2,236 annually out of pocket for metabolic formulas. However, of the 30 families in this group, 17 have private insurance and care coordinators would help them further explore coverage through their health insurer. The resulting change in management of the metabolic formula program may cause a hardship for a small number of families no longer receiving assistance.

Of the 29 adults currently receiving formula payment assistance, 9 have Medicaid and would continue to receive benefits through Medicaid. Another four adults have incomes below 100% federal poverty level and may qualify for some type of medically indigent assistance. Sixteen adults would no longer receive assistance. These adults would pay an average of \$5,338 additional out of pocket costs annually to purchase metabolic formula. Nine of these persons have private health insurance and this may be explored as an option for coverage. This may cause a hardship for some adults no longer receiving assistance.

It is estimated that approximately half of the children in Virginia live in families at or below 300% federal poverty level. Children from families in this income bracket who currently have conditions that will now be identified under the expanded screening panel may now qualify for formula assistance. This is estimated to be an additional 15 children. This would increase VDH costs by \$83,250 annually for those transitioning into formula coverage under the Pool of Funds. Of the anticipated 23 newly identified infants that may be diagnosed with a condition requiring metabolic formula under the revised screening panel, approximately 11 may qualify for Pool of Funds assistance. Some families who receive a diagnosis through newborn screening services will not have access to financial assistance due to their income.

Changing the program model by which formula benefits are administered connects families to a broader service network through Care Connection for Children. It further facilitates financial assistance for not only metabolic formula, but also for other medically necessary services such as medication, hospitalizations, nutritional supplements, and durable medical equipment. Shifting payment assistance for metabolic formula to the same standard used by the children with special health care needs program for other types of assistance applies an equal test to all families with need, regardless of diagnosis. By linking the financial assistance to income, VDH provides financial assistance to those considered

medically indigent and does not subsidize families with moderate to high incomes. This is consistent with how VDH provides basic clinical services (sliding scale for those up to 250% federal poverty level) and how most other assistance programs in the Commonwealth are administered. This model establishes VDH as the payor of last resort.